

### **Remarks/Arguments**

Claims 1-4, 6-10, 63, 65 and 66 were examined and are rejected. Claims 5, 11-31, 42-53, 56-58, 61, 62, 64 and 67-69 were canceled in a previous response. Claims 32-41, 54, 55, 59 and 60 were previously withdrawn in response to a Restriction Requirement. Accordingly, claims 1-4, 6-10, 63, 65 and 66 remain under examination in the application. Applicant respectfully requests that the response be entered pursuant to 37 C.F.R. 1.116.

Claims 1, 2, 63, 65 and 66 are rejected as allegedly being obvious under 35 USC §103(a) over Ehrlich (US 2,801,633), in view of Humphrey (US 5, 807, 401). See Office Action, p. 3.

Claim 1 (and claim 2 by its dependency) recites a lancet device comprising (a) a lancet including a seamless member which is hollowed along a portion of its length, the seamless member having a first end and a second end, wherein the first end of the seamless member is shaped to include first and second sharpened tips, the first and second sharpened tips spaced directly opposite each other on the seamless member and extending parallel to a longitudinal axis of the seamless member, and wherein the seamless member is itself sufficiently rigid to penetrate skin; and (b) a lancet holder arranged and configured on the second end of the lancet to move the lancet a penetration distance to penetrate the skin of a patient with the first and second sharpened tips, wherein the penetration distance is less than a length of the sharpened tips.

Claim 63 (and claims 65 and 66 by their dependency) recites a lancet including a partially hollow member having an outer wall, a first end, a second end and a length therebetween, wherein the outer wall defines a first ground surface and a second ground surface, the first and second ground surfaces each forming a gullet that extends approximately 180 degrees about a longitudinal axis of the lancet forming an

intersection a first tip and a second tip at the first end, and wherein the outerwall is itself sufficiently rigid to draw fluid from a patient; and a lancet holder arranged and configured on the second end of the lancet to move the lancet to a penetration depth to penetrate the skin of a patient with the first and second tips, the penetration depth being less than a length of the gullet measured along the longitudinal axis.

The Examiner has failed to make a *prima facie* case of obviousness for both claims 1 and 63. As noted by the Examiner on page 3 of the Office Action, Ehrlich fails to disclose that the lancet is seamless. However, Ehrlich also fails to disclose that the lancet is a partially hollow member. Ehrlich describes the lancet of Fig. 8 as a blank that is rolled into a tube. Col. 5, lines 17-20. Accordingly, the entire length of the tube of Ehrlich is hollow. Humphrey also fails to disclose a lancet having a partially hollow member. Humphrey discloses polymeric piercing members in either of two broad classes: a solid lancet or a needle with at least one lumen. Humphrey also fails to disclose a partially hollow lancet. Therefore, the combination of Ehrlich and Humphrey does not teach, suggest or render obvious a partially hollow lancet.

Furthermore, both Ehrlich and Humphrey fail to disclose a penetration distance that is less than a length of the sharpened tips as required by the claims. Ehrlich discloses that the point members have a length of between 1 mm and 3 mm as pointed out by the Examiner. Ehrlich also discloses that the bends of the body of the lancet act as stops to limit penetration. Col. 5, lines 26-30. If the bends between tips stops penetration, clearly the entire length of the tip penetrates the skin and is only stopped by the bend. This clearly contradicts the claim language. Humphrey discloses hypodermic needles and lancets that make possible new types of phlebotomy devices and intravenous catheters. (Abstract; Col. 4, lines 16-35). Humphrey's needles allow for deeper penetration. (Col. 3, lines 25-26). The depth of the piercing process can be controlled so that the lancet stopped before "making contact with the supporting base structure. (Col. 8, lines 49-56) Therefore, the combination of Ehrlich and Humphrey

does not teach, suggest or render obvious a penetration distance that is less than a length of the sharpened tips as recited in the claims.

Because the combination of Ehrlich and Humphrey fails to teach, suggest or render obvious as least these elements required by claims 1 and 63, Applicant respectfully submits that claims 1 and 63 and their dependent claims are in condition for allowance, notice of which is requested.

Claims 3, 4 and 6-10 are rejected as allegedly being obvious under 35 USC §103(a) over Ehrlich (US 2,801,633), in view of Ayres (US 3,906,932). See Office Action, p. 5.

Claim 3 (and claims 4 and 6-10 by their dependency) recites a lancet device comprising a lancet including a unitary stainless steel member which is hollowed along a portion of its length, the unitary stainless steel member including a first end and a second end, wherein the first end of the unitary member includes first and second ground surfaces which at least partially define first and second sharpened tips and each define a gullet between the sharpened tips; and a lancet holder arranged and configured on the second end of the lancet to move the lancet a penetration depth to penetrate the skin of a patient with the first and second sharpened tips, the penetration depth being less than a length of the gullet.

Again the Examiner notes that Ehrlich fails to disclose a seamless member. However, as noted above, Ehrlich fails to disclose a member hollowed along a portion of it length. Ehrlich describes the lancet of Fig. 8 as a blank that is rolled into a tube. Col. 5, lines 17-20. Accordingly, the entire length of the tube of Ehrlich is hollow. Ayres also does not teach or suggest a member which is hollowed along a portion of its length. The needle in Ayres was designed to penetrate the rubber stopper of a Vacutainer so that the hollow needle can transport blood from the wound to the Vacutainer, requiring the needle to be hollow along its entire length.

Furthermore, both Ehrlich and Ayres fail to disclose a penetration distance that is less than a length of the sharpened tips as required by the claims. Ehrlich discloses that the point members have a length of between 1 mm and 3 mm as pointed out by the Examiner. Ehrlich also discloses that the bends of the body of the lancet act as stops to limit penetration. Col. 5, lines 26-30. If the bends between tips stops penetration, clearly the entire length of the tip penetrates the skin and is only stopped by the bend. This clearly contradicts the claim language. Ayres also fails to disclose the penetration distance is less than a length of the sharpened tips. Ayres does not discuss penetrating skin. As clearly shown in Fig. 5, "an elevational view . . . showing the needle of the present invention penetrating a stopper of an evacuated tube," the tips of the needle penetrate the entire stopper and come out the other end.

Because the combination of Ehrlich and Ayres fails to teach, suggest or render obvious as least these elements required by claim 3, Applicant respectfully submits that claim 3 and its dependent claims 4 and 6-10 are in condition for allowance, notice of which is requested.

For the reasons set forth above, Applicant traverses the Examiner's rejections and respectfully submits that all pending claims are allowable. Applicant requests the Examiner's early examination of the pending claims in the present application. In the event that the Examiner deems a telephonic discussion would be helpful in advancing the prosecution of the present application, Applicants respectfully request the Examiner to contact Applicants' representative at (248) 244-0163.

Respectfully submitted,

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